5.0 510(k) SUMMARY

In accordance with Title 21 Code of Federal Regulations (21 CFR), Part 807, and in particular, §807.92, the following 510(k) summary is provided for Implicitguide™ Surgical Suture System:

5.1 Submitted By:

NOV 13 2009

Implicit Care, LLC
5920 Friars Road, Suite 102
San Diego, California 92108

Contact: Dionicia B. Reblando, Vice President, RA/QA

Date Prepared: 10/9/2009

5.2 Device Name

Trade or Proprietary Name: Implicitguide™ Surgical Suture System

Common or Usual Name: Nonabsorbable Polyester Suture

Classification Name: Nonabsorbable poly(ethylene terephthalate) surgical suture

5.3 Predicate Devices

The subject device is substantially equivalent, in whole or in part, to the following commercially available predicate device:

- TEVDEK® II Polyester Suture - K001434, K021019; Genzyme Corp.
- Featherlift Extended Length Aptos Threads (Contour Threads) - K041593; Surgical Specialties Corporation

5.4 Device Description

The ImplicitCare Implicitguide™ Surgical Suture System combines USP size 4-0 braided nonabsorbable poly(ethylene terephthalate), or polyester, surgical suture with a set of manual instruments designed to efficiently and accurately place the suture for the purpose of performing approximation of tissue and elevation of subdermis/underlying muscle procedure. All components of the Implicitguide™ Surgical Suture System are provided sterile, and are intended for single use only

The manual instruments consist of the following:

- Tape (marking tape) to aid in marking the skin for needle (Suturod) point of entry locations)- if needed

- Lancet to create a point of entry for needle (Suturod) and suture
- Clearing device to clear subcutaneous ligamentous attachments around the puncture site
- Two (2) stainless steel Suturods™ which, like suture needles, guide the suture through the tissue. Each Suturod™ has an internal light guide which, when connected to the Light Handle, illuminates the distal tip of the Suturod™
- Light Handle which contains an LED light source to connect to Suturod™

5.5 Intended Use

The Implicitguide™ Surgical Suture System is intended for use in soft tissue approximation and elevation of subdermis and underlying muscle.

5.6 Comparison to Predicate Devices

a. The Implicitguide™ Surgical Suture System is equivalent in the intended use to the predicate device, the Featherlift Extended Length Aptos Threads (Contour Threads) except for the surgical technique. The Featherlift Aptos Threads tissue elevation is achieved by tacking to the temporal fascia. The Implicitguide™ Surgical Suture System tissue elevation is achieved by the placement of the suture over the muscle and/or other soft tissues, with subsequent tensioning and knotting of the suture.

b. Suture- The nonabsorbable polyester surgical suture contained in the Implicitguide™ Surgical Suture System is exactly the same suture as the TEVDEK® II polyester suture currently distributed commercially by Teleflex (510[k] nos. K001434 and K021019 by Genzyme Corp.), and meets all requirements of the USP Monograph for Nonabsorbable Surgical Suture

c. Device design, physical configuration and materials-Comparisons of design characteristics and physical configurations of the predicate devices have established that Implicitguide™ Surgical Suture System is substantially equivalent in design, physical configuration and materials of composition. The predicate device has two needles, one needle attached at each end of suture. The Implicitguide™ Surgical Suture System has two needles called Suturods, one attached to each end of the suture at the midpoint of the needle. Materials of construction are both stainless steel and materials that have long history of successful use in medical devices. See **attachment 1, or** Addendum 3, Section 10.4 Device Comparison table.

5.7 Summary of Non-Clinical Test

a. The nonabsorbable polyester surgical suture contained in the Implicitguide™ Surgical Suture System is exactly the same suture as the TEVDEK® II polyester suture currently distributed commercially by Teleflex (510[k] nos. K001434 and K021019 by Genzyme Corp.).

Teleflex Medical has issued a certification to ImplicitCare, that tests on the Teleflex suture have been completed, test profile and results comply with AAMI/ISO 10993-1 requirements and FDA's Blue Book memorandum (G95-1) to assure safe patient contact of an Implant Device contacting Tissue, Bone, or Blood permanently. All results are acceptable. **See attachment 2.**

The following are the tests conducted:

- Physico-chemical: Plastics, USP
- Cytotoxicity:-ISO MEM Elution
- Sensitization:-ISO Murine Lympth Node Asay
- Irritation: ISO Intracutaneous Reactivity Test
- Systemic Toxicity: ISO Acute Systemic Injection Test
- Genotoxicity: ISO Salmonella typhyimurium Reverse Mutation
- Hemocompatibility: Hemolysis test (NIH Method)
- Pyrogen: ISO Materials Mediated Rabbit Pyrogen
- Implantation: 7 day and 90 day Muscle implant

These tests demonstrate that the suture contained in the Implicitguide™ Surgical Suture System is as safe as the predicated devices.

Since the nonabsorbable polyester surgical suture contained in the Implicitguide™ Surgical Suture System is exactly the same suture as the TEVDEK® II, and, the subject device will meet all requirements of USP XXXI <871> *Needle attachment – Sutures.* As such, no additional non-clinical testing is necessary to further demonstrate substantial equivalence to other polyester sutures marketed in the U.S.

b. Cadaver Tests. The study was conducted on four cadavers, two females and two males. The two males are both 58 years old and the females are 92 and 84 years old. The procedure was conducted by Board Certified plastic surgeons, Dr. Gregory Mueller and Dr. Sherrell Aston. Both of their CV's are on file. Procedure was conducted on August 31, 2009, in University of Maryland, State Anatomy Board, 655 West Baltimore Street Room B-023, Baltimore, MD 21201

Tests completed:

1. Brow elevation and shaping.
2. Suturod: Trans-Illumination and color of light.
3. Tensile strength of medial platysmal border muscles, and facial retaining ligaments.

Test results are acceptable and test reports are on file. **See attachment 3 for summary**. These tests were conducted to demonstrate substantial equivalence to predicate device, Contour Threads, with added advantage of the Suturod light transillumination.

c. EMC Evaluation for the (Surgical) Light tool of Suturod (Needle).

This evaluation was conducted in accordance with the specifications for medical electrical equipment as specified by International Electrotechnical Commission (IEC) and the European Committee for Electrotechnical Standardization (CENELEC).

Test specification: Radio Frequency Emissions and Electromagnetic Immunity Tests in accordance with requirements of IEC 60601-1-2:2002/A1:2004 and EN60601-1-2:2007

Test Results: All test required passed requirements. **See attachment 4** for Certificate and summary of test results. Complete test report on file.

This report demonstrates the safety of the Suturod.

d. Design Verification Tests

Design Verification Tests have been completed. All test results are acceptable.

The following test report are on file. See **attachment 5** for summary of Design validation

-TR090109-01 Design Verification Clearing Tool Torque Test

-TR090109-02 Design Verification Lancet Blade Puncture Test

-TR090109-03 Design Verification Suture Length Test

-TR090109-04 Design Verification Suture Attachment force Test

-TR090109-05 Design Verification Suturod Bending Test

-TR090109-06 Design Verification Light Intensity Test

-TR090109-07 Design Verification Light on- time Test

These tests demonstrate that the device meets design and USP requirements

5.8 Summary of Clinical Tests

No clinical testing was conducted to support this submission.

5.9 Conclusions

The results of our comparison demonstrated the substantial equivalence of the subject device to the identified predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV 13 2009

Implicit Care, LLC
% Ms. Dionicia B. Reblando
Vice President, RA/QA
5920 Friars Road, Suite 102
San Diego, California 92108

Re: K091061
Trade/Device Name: Implicitguide™ Surgical Suture System
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: October 23, 2009
Received: October 28, 2009

Dear Ms. Reblando:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091061

Device Name: Implicitguide™ Surgical Suture System

Indications for Use:

The Implicitguide™ Surgical Suture System is indicated for use in soft tissue approximation and elevation of subdermis and underlying muscle.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091061